

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner rejected claims 1-33 under 35 U.S.C. § 112, first paragraph, for lack of enablement. More specifically, the Examiner asserts that the specification, while being enabling for compounds and methods for modulating occludin-mediated cell adhesion, does not provide enablement for methods for enhancing the delivery of a drug to a tumor in a mammal, methods for treating cancer in a mammal, or a method for enhancing immune cell infiltration into a tumor in a mammal. The Examiner also asserts that the scope of the claimed invention is not commensurate with the disclosure in the specification, insofar as the examples set forth (Examples 1-6, pages 50-57) are not representative examples of the methods claimed. In addition, the Examiner asserts that the specification does not provide sufficient guidance to extrapolate the examples set forth to the methods of use in a mammal as claimed.

Applicants respectfully traverse this ground of rejection. With respect to enablement, nothing more than objective enablement is required in order to meet the requirements of 35 U.S.C. § 112, first paragraph. In particular, as stated by the Board of Patent Appeals and Interferences:

As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. *Staehelin v. Secher*, 24 USPQ 2d 1513, 1516 (B.P.A.I. 1992) (citing *In re Marzocchi* 169 USPQ 367, 369 (C.C.P.A. 1971)) (emphasis original).

In the instant case, a reasonable basis that the specification lacks enablement has not been established in the Office Action. Although the Examiner asserts that the therapeutic art area was unpredictable, no specific support is provided for doubting that one of ordinary skill in the art would be able to use the claimed methods without undue experimentation, particularly in

view of the Examiner's acknowledgement that the specification is enabling for compounds and methods of modulating occludin-mediated cell adhesion. Should this ground of rejection be maintained, Applicant respectfully request that specific support be provided for the basis that the specification lacks enablement.

Additionally, Applicants respectfully submit that the subject specification provides sufficient disclosure to enable the claimed methods of using cell adhesion modulating agents. For instance, the section entitled "Modulating Agent Methods of Use" (*see*, page 41, line 11 to page 49, line 14) contains a detailed description on how to use cell adhesion modulating agents, including administration methods, formulations and dosages. More specifically, the description for methods for enhancing the delivery of a drug to a tumor in a mammal is provided, for example, on page 20, line 43 to page 44, line 30; the description for methods for treating cancer in a mammal on page 45, line 1 to page 46, line 9; the description for methods for enhancing immune cell infiltration in a tumor page 46, line 10 to page 47, line 9. In addition, Examples 3-6 illustrate methods of using cell adhesion modulating agent to increase vasopermeability *in vivo*, to modulate the formation of tight junctions in epithelial cells, to increase neutrophil migration of endothelial cells, and to increase transendothelial permeability, respectively. Accordingly, those of ordinary skill in the art would readily conclude that the specification provides sufficient guidance for one to enhance drug delivery to a tumor, to treat cancer, or to enhance immune cell infiltration into a tumor in a mammal using cell adhesion modulating agents.

Furthermore, Applicants respectfully submit that the disclosure of the subject specification is commensurate with the scope of the claims and that no undue experimentation is required to practice the invention. The mere fact that exemplified embodiments in the specification are more limited than those recited in the claims does not provide sufficient reason for the Examiner to hold the claims non-enabled. An Applicant is *not* required to specifically exemplify all embodiments of the invention that are encompassed by the invention. The requirements of 35 U.S.C. § 112, first paragraph, can be fulfilled by the use of *illustrative examples or broad terminology*. *In re Anderson*, 176 USPQ 331 (CCPA 1973).

Accordingly, Applicants respectfully submit that this rejection under 35 U.S.C. § 112, first paragraph, has been obviated and request it be withdrawn.

Applicants respectfully submit that all of the claims remaining in the application are now allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. If, however, the Examiner has any remaining concerns regarding the allowability of the remaining claims, the Examiner is encouraged to telephone the undersigned at (206) 622-4900.

Respectfully submitted,

Seed Intellectual Property Law Group PLLC

A handwritten signature in black ink, appearing to read 'W. Christiansen', is written over a horizontal line.

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